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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,750	01/16/2001	Ichiro Azuma	0020-4802P	7730
2292 7590 01/18/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/18/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary**

Application No.

09/743,750

Applicant(s)

AZUMA ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-8, 10, 11 and 13-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5-11 and 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 11, 2006 has been entered. Applicant's amendment, response and declaration submitted under 1.1.32 filed October 11, 2006 is acknowledged. Claim 21 has been amended. Claims 1-3, 5-8, 10-11, 13-20 have been withdrawn from consideration as being directed to a non-elected invention. Claims 4, 9 and 12 have been canceled. Applicant's supplemental response filed October 25, 2006 and resubmission of the declaration filed under 1.1.32 (for photo quality) is also acknowledged.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

***Interview***

3. An interview was held with Mr. Nuell on August 23, 2006. In this interview Applicant explained the essence of the invention. Applicant asserted that the invention was patentable over the prior art of record. Declarations submitted by Dr. Kawabe and Dr. Nomura were discussed. Applicant provided new photocopies of the photographs were included in the declarations for clarity purposes. The Examiners informed Mr. Nuell that the comments made in the interview as well as the response would be considered. No determination of patentability was made in the interview. See attached interview summary.

***Rejections Withdrawn***

4. In view of Applicant's remarks the following rejections are withdrawn:
- (a) The rejection under 35 U.S.C. 102(b) of claims 21 and 23-26, pages 5-7, paragraph 5 of the Final Office action.
  - (b) The rejection under 35 U.S.C. 102(b) of claims 21 and 23-26, pages 10-12, paragraph 7 of the Final Office action.

***Rejections Maintained***

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 21- 26 for the reasons set forth on pages 3-5 paragraph 4 of the Final Office Action.

The rejection was on the grounds that Yamamura et al teach compositions comprising *Nocardia ruba* cell wall skeleton, squalene, a suspending agent and dispersing agent (see the Abstract). Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis* (column 2, lines 15-21). Yamamura et al teach the composition was prepared using suspending agents such as Tween and Span (surfactants) (column 2, lines 54-68). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100  $\mu\text{m}$  or less is homogeneously dispersed" and "wherein the particle diameter is about 25  $\mu\text{m}$ " would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalene). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yamamura et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A) Applicant urges that the Declaration evidence of record established that failure to include an organic solvent in the step of dispersing the CWS component in oil results in the appearance of very large particles in the resulting emulsion and the resulting emulsion has a lower stability. Applicant urges that the organic solvent used in the present invention results in an emulsion free of large particles (i.e. particles over 100  $\mu\text{m}$  in diameter as shown in Figures 1 and 2 of the specification) and the emulsion is stable for a longer time.

B) Applicant refers to the declaration submitted by Dr. Koseki to support their position. Applicant urges that the declaration discloses experiments comparing the present oil-in-water emulsion to the oil-in-water emulsions of the prior art. Applicant urges that the particle sizes of Yamamura et al are larger than those of the claimed invention.

C) Applicant urges that the product of Yamamura et al did not form a uniform emulsion. Applicant refers to Experiment 2 and Figure 3 of Dr. Koseki's declaration to try to point out differences between the claimed products and the products of the prior art.

Examiner Response to Applicant's Comments

Applicant's arguments filed October 11, 2006 have been fully considered but they are not persuasive.

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A) It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a *Bacillus Calmette-Guerin* cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

To address Applicant comment regarding, Yamamura et al, Yamamura et al teach compositions comprising *Nocardia rubra* cell wall skeleton, squalene, a suspending agent and dispersing agent. Yamamura et al teach that cell wall skeleton used in the invention can be derived from *Mycobacterium bovis*. Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

To address Applicant's comment regarding stability of the emulsion, it should be noted that there are no limitations in the claims regarding stability.

B) To address Applicant's comments regarding the Declaration of Dr.Koseki, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. The declaration of Dr. Koseki under 37 CFR 1.132 filed October 11, 2006 is insufficient to overcome the rejection of claims 21-26 because the product of the prior art and the claimed invention are the same and no

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structural difference have been established to point out the differences between the products.

C) To address Applicant comments regarding Experiment 2, figure 3 of the declaration submitted by Dr. Koseki, it appears this declaration is submitted to show difference between the claimed product and the product of the prior art in terms of uniformity of the product. It should be noted that there are no limitations in the claims that recite any level of uniformity. It should also be noted the oil-in-water emulsions of the prior art produce particles that are of the same size as particles formed in the claimed oil-in-water emulsion. It should be further noted that the emulsions of the claimed invention and the emulsions of the prior art are the same. Therefore, uniformity is not a patentable distinction between the claimed invention and the prior art.

6. The rejection under 35 U.S.C. 102(b) is maintained for claims 21- 26 for the reasons set forth on pages 8-10 paragraph 6 of the Final Office Action.

The rejection was on the grounds that Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as "wherein the emulsion is negative for agglutination reaction with lectin", "having an particle diameter of about 100  $\mu\text{m}$  or less is homogeneously dispersed" and "wherein the particle diameter is about 25  $\mu\text{m}$ " would be inherent in the teachings of the prior art. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil (squalane). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be

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of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Yarkoni et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

#### Applicant's Arguments

A) Applicant urges that the Declaration evidence of record established that failure to include an organic solvent in the step of dispersing the CWS component in oil results in the appearance of very large particles in the resulting emulsion and the resulting emulsion has a lower stability. Applicant urges that the organic solvent used in the present invention results in an emulsion free of large particles (i.e. particles over 100  $\mu\text{m}$  in diameter as shown in Figures 1 and 2 of the specification) and the emulsion is stable for a longer time.

B) Applicant refers to the declaration submitted by Dr. Koseki to support their position. Applicant urges that the declaration discloses experiments comparing the present oil-in-water emulsion to the oil-in-water emulsions of the prior art. Applicant urges that the particle sizes of Yarkoni et al are larger than those of the claimed invention.

C) Applicant urges that product of Yarkoni et al did not form a uniform emulsion.

Applicant refers to Experiment 2 and Figure 3 of Dr. Koseki's declaration to try to point out differences between the claimed products and the products of the prior art.

Examiner Response to Applicant's Comments

Applicant's arguments filed October 11, 2006 have been fully considered but they are not persuasive.

A) It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which comprises a *Bacillus Calmette-Guerin* cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

[E]ven though product-by-pro-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

To address Applicant comment regarding, Yarkoni et al, Yarkoni et al teach oil-in-water emulsions comprising *Mycobacterium bovis* BCG cell walls, squalane and Tween (surfactant) (page 881). Claim limitations such as particle diameter of droplets would be inherent in the teachings of the prior art. Thus, the prior art anticipates the claimed invention.

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B) To address Applicant's comments regarding the Declaration of Dr. Koseki, it appears the declaration is submitted to argue the difference in particle size of the BCG-CWS composition. The declaration compares using solvents and not using solvents to prepare the BCG-CWS composition. The declaration of Dr. Koseki under 37 CFR 1.132 filed October 11, 2006 is insufficient to overcome the rejection of claims 21-26 because the product of the prior art and the claimed invention are the same and no structural difference have been established to point out the differences between the products.

C) To address Applicant comments regarding Experiment 2, figure 3 of the declaration submitted by Dr. Koseki, it appears this declaration is submitted to show difference between the claimed product and the product of the prior art in terms of uniformity of the product. It should be noted that there are no limitations in the claims that recite any level of uniformity. It should also be noted the oil-in-water emulsions of the prior art produce particles that are of the same size as particles formed in the claimed oil-in-water emulsion. It should be further noted that the emulsions of the claimed invention and the emulsions of the prior art are the same. Therefore, uniformity is not a patentable distinction between the claimed invention and the prior art.

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7. The rejection under 35 U.S.C. 102(b) is maintained for claims 21- 26 for the reasons set forth on pages 15-17 paragraph 8 of the Final Office Action.

The rejection was on the grounds that Zbar et al teach compositions comprising BCG cell walls and mineral droplets (see the Abstract and pages 831-832). Zbar et al teach that the oil droplets of the prior art ranged from less than 1  $\mu$  to greater than 15  $\mu$ . Therefore, the claim limitation "the particle diameter of an oil droplet is 100  $\mu$ m or less taught by the prior art. The claim limitation wherein the emulsion is negative for agglutination reaction with lectin" would be inherent in the teachings of the prior art. Claims limitations such as "(a) stirring a mixture of a Bacillus Calmette-Guerin cell wall skeleton, an oil, and an organic solvent to disperse the Bacillus Calmette-Guerin cell wall skeleton in the mixture; (b) evaporating off the organic solvent to form an oil wherein the Bacillus Calmette-Guerin cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is encapsulated in the oil; and then, (c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture" are being viewed as process limitations. The products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same functional characteristics, i.e. oil-in-water compositions comprising cell wall skeleton and oil. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Zbar et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's emulsion with the emulsion of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the emulsion of the prior art does not possess the same material structural and functional characteristics of the claimed emulsion). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

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- B) Applicant refers to the declaration submitted by Dr. Koseki to support their position. Applicant urges that the declaration discloses experiments comparing the present oil-in-water emulsion to the oil-in-water emulsions of the prior art. Applicant urges that the particle sizes of Zbar et al are larger than those of the claimed invention.
- C) Applicant urges that product of Zbar et al did not form a uniform emulsion. Applicant refers to Experiment 3 and Figure 4 of Dr. Koseki's declaration to try to point out differences between the claimed products and the products of the prior art.

Examiner Response to Applicant's Comments

Applicant's arguments filed October 11, 2006 have been fully considered but they are not persuasive.

- A) It is the Examiner's position that Applicant is urging process limitations in a product claim. The claims are directed to an oil-in-water emulsion (a product) which

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comprises a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil. It should be remembered that MPEP 2113 states:

[E]ven though product-by-product claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-product claim is the same as or obvious from the a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

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***New Ground of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 21-26 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21, in particular recites "...crude particles...". The instant specification at page 18 discloses that "crude particles that are visible have usually a diameter of 100µm or more". Do all crude particles have usually a diameter of 100µm or more? What is meant by "crude particles"? Clarification and/or correction is required.

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**Status of Claims**

9. No claims allowed.

**Conclusion**

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 273-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Thursday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
January 7, 2007

  
NITA MINNIFIELD  
PRIMARY EXAMINER